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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/921,233	08/01/2001	Christian Knopfle	60,500-072	6017

27305 7590 04/06/2009

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EXAMINER	
PHILOGENE, PEDRO	
ART UNIT	PAPER NUMBER
3733	
MAIL DATE	DELIVERY MODE
04/06/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/921,233	KNOPFLE ET AL.	
	Examiner	Art Unit	
	Pedro Philogene	3733	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 January 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,5,6,10,11,29-31,38-41 and 44-49* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,5,6,10,11,29-31,38-41,44-49* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114 was filed in this application after a decision by the Board of Patent Appeals and Interferences, but before the filing of a Notice of Appeal to the Court of Appeals for the Federal Circuit or the commencement of a civil action. Since this application is eligible for continued examination under 37 CFR 1.114 and the fee set forth in 37 CFR 1.17(e) has been timely paid, the appeal has been withdrawn pursuant to 37 CFR 1.114 and prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on 1/2/09 has been entered.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1,6, 10,11, 29-31, 38-41,44, 48, 49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Manthrop et al. (5,916,217) in view of Bremer (5,549,620).

With respect to claims 1, 29-31, 38-41, 48,49 Manthrop et al disclose a self-retaining implant for attaching a bone cover or a bone fragment to a skull, the implant (110) comprising a support element (112,118) having an upper side and a lower side an extension (124) extending substantially at a right angle from the lower side of the support element to an end remote from the support element and substantially straight between the support element and the end; at least one spike (132) such that the spike

can be driven laterally into the bone cover or bone fragment prior to positioning the bone cover or bone fragment adjacent to the skull; as set forth in column 3, lines 32-57; as best seen in Fig. 3; wherein the support element comprises two support arms; as best seen in FIG.3, extending in opposite direction from the extension (124) with the first of the two support arms defining a screw hole therein for receiving a fastener (140) to secure the first support arm to the skull after the spike has been driven laterally into the bone cover or bone fragment and after positioning the bone cover or bone fragment adjacent to the skull and the second of the two support arms for cooperating with the bone cover or bone fragment when driving the spike laterally into the bone cover or bone fragment; as set forth in column 3, lines 32-57.

It is noted that Manthrop et al did not teach of at least one spike extending substantially parallel to the support element, as claimed by applicant. However, Manthrop et al teach of a spike forming an angle with the extension. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to reach the 90 degrees angle, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, USPQ 233; or discovering an optimum value of a result effective variable involves only routine skill in the art. In re Boesch, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

It is noted that Manthrop does not teach of an implant delivery device adapted to receive the implant and apply a force to the implant to drive the at least one spike laterally into the bone cover or bone fragment, as claimed by applicant. However, in a

similar art, Bremer provides the evidences of the use of an implant delivery device (40) that is capable of receiving an implant and applying a force to the implant to drive the at least one spike (25,26) laterally into the bone cover or bone fragment, as claimed by applicant to grip and place the implant in the skull.

Therefore, given the teaching of Bremer, it would have been obvious to one having ordinary skill in the art, at the time the invention was made to modify the device of Manthrop, as taught by Bremer, by using an implant delivery device, instead of manually, to grip and place the implant in the skull.

With respect to claim 6, Manthrop et al discloses an implant wherein the spike extends from an end of the extension remote from the support element; as best seen in FIG.3.

With respect to claim 44, the method steps, as set forth, would have been obviously carried out in the operation of the device, as set forth above.

Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Manthrop et al. (5,916,217) in view of Bremer (5,549,620) in of Hair (6,197,037).

With respect to claim 5, it is noted that the above combination of references did not teach of a lower side of the support having a concave or spherically curved at least in section; as claimed by applicant. However, in a similar art, Hair evidences the use of a fastener having a concave or spherically curved lower side to tightly engage the outer surface of the bone and promote gripping action.

Therefore, given the teaching of Hair, it would have been obvious to one having ordinary skill in the art at the time the invention was made to incorporate the curved

lower surface of the device of Hair in the device of Manthrop et al. side to tightly engage the outer surface of the bone and promote gripping action.

Claims 10, 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Manthrop (5,916,217) in view of Bremer (5,549,620) in view of Hair (6,197,037) in view of Pohndorf et al. (5,904,683).

With respect to claim 10, it is noted that the above combination of references did not teach of a support element having a thickness increasing in the direction of the screw hole; as claimed by applicant. However, Pohndorf et al. evidence the use of a support element having a thickness increasing in the direction of the screw hole to strengthen the support element for receiving a screw and stabilize a bone.

Therefore, given the teaching of Pohndorf et al., it would have been obvious to one having ordinary skill in the art at the time the invention was made to incorporate the increasing thickness of Pohndorf et al in the support element of Manthrop/Hair to strengthen the support element for receiving a screw and stabilize a bone.

With respect to claim 11, Pohndorf et al teach a screw hole that is spherically curved, as best seen in FIG.11.

Claims 45-47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Manthrop (5,916,217) in view of Bremer (5,549,620) in view of Cullen (2,065,659).

It is noted that the above combination of references did not teach of a receiving element defining a slot at one end there of and a driving in mechanism coupled to the receiving element for driving the at least one spike element of the implant laterally into the bone cover or bone fragment and wherein the driving-in mechanism comprises a

striking element displaceable against a spring force. However, in similar art, Cullen provides the evidences of the use of a receiving element defining a slot at one end there of and a driving in mechanism coupled to the receiving element for driving the at least one spike element of the implant laterally into the bone cover or bone fragment and wherein the driving-in mechanism comprises a striking element displaceable against a spring force to drive a tack into bone.

Therefore, given the teaching of Cullen, it would have been obvious to one having ordinary skill in e art at the time the invention was made to modify the device of Manthrop/Bremer, as taught by Cullen, by the use of a receiving element defining a slot at one end there of and a driving in mechanism coupled to the receiving element for driving the at least one spike element of the implant laterally into the bone cover or bone fragment and wherein the driving-in mechanism comprises a striking element displaceable against a spring force to drive a tack into bone.

Response to Amendment

Applicant's arguments with respect to claims 1, 5, 6, 10, 11, 29-31, 38-41, 44-49 have been considered but are moot in view of the new ground(s) of rejection. Since applicant is claiming an implant delivery device that “adapted to” or “configured to”; the examiner would like to bring to applicant’s attention that the recitation that an element is “adapted to” or “configured to” perform a function has been held to be not a positive limitation but requires the ability to so perform. It does not constitute a limitation in any patentable sense. In addition, the manner in which a device is intended to be employed,

does not differentiate the claimed apparatus from the prior art apparatus satisfying the claimed structural limitations. Ex parte Masham, 2 USPQ2d 1647 (1887).

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

5,501,685	3-1996	Spetzler
6,969,391	11-2005	Gazzani

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pedro Philogene whose telephone number is (571) 272-4716. The examiner can normally be reached on Monday to Friday 6:30 AM to 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on (571) 272 - 4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Pedro Philogene/
Primary Examiner, Art Unit 3733
April 2, 2009